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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,718	02/13/2002	Shubh D. Sharma	70025-02-US02	9717

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PEACOCK MYERS AND ADAMS P C
P O BOX 26927
ALBUQUERQUE, NM 871256927

EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,718	SHARMA ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2003 and 10 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-63* is/are pending in the application.

4a) Of the above claim(s) *1,3-5,9-17,19,21-25,34-36 and 41-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,7,8,18,20,26-33 and 37-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20020708*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election of Group II and the species R_1-Bbb-Aaa-Ccc-R_2 in the reply filed on May 10, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 3-5, 9-17, 19, 21-25, 34-36, and 41-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 10, 2004.

2. The amendment to the claims filed May 10, 2004 was in improper format. The text of canceled claim 6 should not have been included in the amendment. See 37 CFR 1.121(c)(4)(i).

3. The Sequence Listing filed March 28, 2003 is approved.

4. The declaration under 37 CFR 1.63 filed February 13, 2002 gives an incorrect filing date for provisional application 60/148,994. The correct filing date for the provisional application is August 13, 1999. However, because the provisional application is otherwise sufficiently identified in the declaration, and because there is no requirement that a provisional application be cited in an oath or declaration under 37 CFR 1.63, the declaration is approved.

5. The disclosure is objected to because of the following informalities: While the sequence listing filed March 28, 2003 contains 69 sequences, the examiner is unable to locate any sequence identified as SEQ ID NO:54. At page 10, lines 15 and 16, "cyclopentamethylene" is misspelled. In Table 1 of the specification (see pages of the preliminary amendment filed March 28, 2003), "naphthalene" and "adamantane" are misspelled in several of the compound names. SEQ ID NOS must be inserted after all of amino acid sequences subject to the sequence

disclosure rules, including those at page 56, line 37, and page 57, line 4. See 37 CFR 1.821(d). Appropriate correction is required.

6. Claims 2, 7, 8, 18, 20, 26-33, and 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meaning of the term "determined" at claim 2, line 2, is not known. The term is not defined in Applicants' specification, and it is not clear what distinguishes between a determined biological-function domain and an undetermined one. For example, it is not clear what is to be determined and when, who is to do the determining, and how it is to be determined. There is no antecedent basis in the claim for the phrase "The composition of claim 2" in claims 7 and 8. Claim 2 is drawn to a peptide and salts thereof, not a composition. There is no antecedent basis in the claims for the phrase "the metal ion-binding amino acid sequence" at claim 8, line 3. Note that claim 2, upon which claim 8 depends, recites a "metal ion-binding domain" rather than a "metal ion-binding amino acid sequence".

7. Claims 18, 20, 26-33, and 37-40 are objected to because of the following informalities: At claim 18, line 10, "molecule" should be changed to "peptide" in order to be consistent with the terminology used in the preamble of the claim. Appropriate correction is required.

8. Claim 39 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to other claims in the alternative only. Note that claim 39 is dependent upon both claim 18 and claim 37. See MPEP § 608.01(n), especially the example at (I)(B)(3).

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 7, 8, 18, 20, 26-33, and 37-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/640,755. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '755 application anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Instant claims 2, 7, 8, 18, 20, 26-33, and 37-40 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/148,994 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose peptides in general in which the biological-function domain is co-extensive with at least a portion of the metal ion-binding domain, and does not disclose each of the generic formulas recited in instant claim 18, and in particular does not disclose the formula corresponding to the elected species R_1-Bbb-Aaa-Ccc-R_2. Accordingly, Sharma (U.S. Patent No. 5,891,419), the Fabris et al article (Inorganic Chemistry, Vol. 38, pages 1322-1325), and the Giblin et al article (PNAS, Vol. 95, pages 12814-12818) are available as prior art against these claims under 35 U.S.C. 102(b), and the Shi et al abstract (Abstracts Of Papers, American Chemical Society,

218th ACS National Meeting, Part 1, Abstract MEDI 257) and Granoff et al (U.S. Patent No. 6,048,527) are available as prior art against these claims under 35 U.S.C. 102(a).

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 2, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Sharma (U.S. Patent No. 5,891,418). Sharma teaches peptides in Examples 44 and 46 which bind to melanocortin receptors and which complex with metals. In view of the similarity in structure and function between the peptides of Sharma and the instant claimed peptides, the peptides of Sharma are deemed inherently to be conformationally constrained upon complexing with a metal ion, and to be substantially more specific for a melanocortin receptor in complexed in compared to uncomplexed form, to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides of Sharma and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than those of the unclaimed peptides.

13. Claims 2, 7, 8, 18, 20, 26-30, 32, 33, 37, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by the Fabris et al article (Inorganic Chemistry, Vol. 38, pages 1322-1325). The Fabris et al article teaches zinc-finger peptides comprising the sequence Pro-Tyr-Lys-Cys, in which the Pro corresponds to Applicants' R_1, the Tyr corresponds to Applicants' Bbb, the Lys corresponds to Applicants' Aaa, the Cys corresponds to Applicants' Ccc, and the remainder of

the zinc finger peptides comprise Phe, an amino acid with an aromatic sidechain, which remainder corresponds to Applicants' R_2. The zinc-finger peptides are amidated at their C-terminus. The zinc-finger peptides complex with and are conformationally restrained by zinc. See, e.g., Figure 1. With respect to instant claim 27, the Pro residue in the zinc-finger peptides of the Fabris et al article comprises a $-(CH_2)_3-$ group in its sidechain, which is a linear alkyl chain. With respect to instant claim 30, the Tyr residue in the zinc finger peptides of the Fabris et al article is a derivative, analog, and/or homolog of the specific residues recited in Applicants' claim because it comprises an aromatic sidechain. Note that Applicants' specification does not define "derivative", "analog", or "homolog" so as to exclude this interpretation. With respect to instant claim 37, the remainder of the zinc finger peptides of the Fabris et al article is a derivative, analog, and/or homolog of the specific residues recited in Applicants' claim because it comprises a Phe residue. Note that Applicants' specification does not define "derivative", "analog", or "homolog" so as to exclude this interpretation. In view of the similarity in structure and function between the zinc-finger peptides of the Fabris et al article and Applicants' claimed peptides, the zinc-finger peptides are deemed inherently to have a determined biological-function domain, to have a biological-function domain which is co-extensive with at least a portion of a metal ion-binding domain, and to be substantially more specific for one or more melanocortin receptors when in the complexed state in comparison to the uncomplexed state, to the same extent claimed by Applicants. In view of the similarity in structure between the zinc-finger peptides of the Fabris et al article and Applicants' claimed peptides, the Lys residue and the Tyr residue of the zinc-finger peptides of the Fabris et al article are deemed inherently to provide an N for metal ion complexation to the same extent claimed by Applicants. Note that although the

Lys and Tyr residues do not provide an N for metal ion complexation in the specific examples illustrated by Figure 1 of the Fabris et al article, this does not mean that there are no metals or conditions under which the Lys and/or Tyr residues in the zinc-finger peptides of the Fabris et al article will not provide an N for metal ion complexation. Note that Applicants' claims 29 and 32 do not specify any particular metals or conditions under which metal ion complexation must occur. Sufficient evidence of similarity is deemed to be present between the zinc-finger peptides of the Fabris et al article and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than the zinc-finger peptides of the Fabris et al article.

14. Claims 2, 7, 8, 18, 20, 27-30, 32, 33, 37, and 38 are rejected under 35 U.S.C. 102(a) as being anticipated by the Shi et al abstract (Abstracts Of Papers, American Chemical Society, 218th ACS National Meeting, Part 1, Abstract MEDI 257). The Shi et al abstract teaches an acetylated and amidated peptide, His-Phe-Arg-Cys-Trp, complexed with rhenium, and which is highly specific for MCR-1.

15. Claims 2, 7, 8, 18, 20, 26-29, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by the Giblin et al article (PNAS, Vol. 95, pages 12814-12818). The Giblin et al article teaches the peptides NAc-Cys-Glu-His-D-Phe-Arg-Trp-Cys-Lys-Pro-Val-NH_2 and NAc-Cys-Cys-Glu-His-D-Phe-Arg-Trp-Cys-Lys-Pro-Val-NH_2, which correspond to Applicants' peptide of the formula R_1-Fff-Aaa-Ggg-Ccc-R_5, where NAc-Cys-Glu-His and NAc-Cys-Cys-Glu-His, respectively, are R_1; D-Phe is Fff; Arg is Aaa; Trp is Ggg; Cys is Ccc; and Lys-Pro-Val-NH_2 is R_5 which is a substituted amide or which comprises an L- or D-amino acid. The peptides are complexed and cyclized with Re or Tc. The complexed peptides are specific for α-

MSH receptors. See, e.g., the Abstract; page 12815, column 1, first full paragraph; and Figure 1. In view of the similarity in structure and function between the peptides of the Giblin et al abstract and Applicants' claimed peptides, the peptides of the Giblin et al abstract are deemed inherently to have a determined biological-function domain, to have a biological-function domain which is co-extensive with at least a portion of a metal ion-binding domain, and to be substantially more specific for one or more melanocortin receptors when in the complexed state in comparison to the uncomplexed state, to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides of the Giblin et al abstract and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than the peptides of the Giblin et al abstract.

16. Claims 2, 8, 18, 26-30, 32, 37, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Deghenghi (U.S. Patent No. 5,668,254). Deghenghi teaches a peptide in claim 10 which corresponds to Applicants' elected peptide formula. In particular, D-Phe-Cys-Tyr corresponds to Applicants' R_1, D-2-methyl-Trp corresponds to Applicants' Bbb, Lys corresponds to Applicants' Aaa, Cys corresponds to Applicants' Ccc, and Trp-NH_2 corresponds to Applicants' R_2. The amino acids which correspond to Applicants' R_1 also comprise various alkyl, aryl, and aralkyl chains. With respect to instant claim 30, the D-2-methyl-Trp residue in the peptide of Deghenghi is a derivative, analog, and/or homolog of the specific residues recited in Applicants' claim because it comprises an aromatic sidechain. Note that Applicants' specification does not define "derivative", "analog", or "homolog" so as to exclude this interpretation. In view of the similarity in structure between the peptide of Deghenghi and Applicants' claimed peptides, the peptide of Deghenghi is deemed inherently to have a

determined biological-function domain, to have a biological-function domain which is co-extensive with at least a portion of a metal ion-binding domain, and to be substantially more specific for one or more melanocortin receptors when in the complexed state in comparison to the uncomplexed state, to the same extent claimed by Applicants. In view of the similarity in structure between the peptide of Deghenghi and Applicants' claimed peptides, the Lys residue and the D-2-methyl-Trp residue of the peptide of Deghenghi are deemed inherently to provide an N for metal ion complexation to the same extent claimed by Applicants. Note that although the Lys and D-2-methyl-Trp residues do not provide an N for metal ion complexation in any of the examples of Deghenghi, this does not mean that there are no metals or conditions under which the Lys and/or D-2-methyl-Trp residues in the peptide of Deghenghi will not provide an N for metal ion complexation. Note that Applicants' claims 29 and 32 do not specify any particular metals or conditions under which metal ion complexation must occur. Sufficient evidence of similarity is deemed to be present between the peptide of Deghenghi and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than the peptide of Deghenghi.

17. Claims 2, 8, 18, 26-30, 32, 37, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Keri et al (U.S. Patent Application Publication 2001/0009899). Keri et al teach peptides in claim 4, VZ-924 and BAH-52, which correspond to Applicants' elected peptide formula. In particular, D-Phe-Cys-Tyr corresponds to Applicants' R_1, D-Trp corresponds to Applicants' Bbb, Lys corresponds to Applicants' Aaa, Cys corresponds to Applicants' Ccc, and Trp-NH_2 and β-Nal-NH_2, respectively, correspond to Applicants' R_2. The amino acids which correspond to Applicants' R_1 also comprise various alkyl, aryl, and aralkyl chains. With respect

to instant claim 30, the D-Trp residue in the peptides of Keri et al is a derivative, analog, and/or homolog of the specific residues recited in Applicants' claim because it comprises an aromatic sidechain. Note that Applicants' specification does not define "derivative", "analog", or "homolog" so as to exclude this interpretation. In view of the similarity in structure between the peptides of Keri et al and Applicants' claimed peptides, the peptides of Keri et al are deemed inherently to have a determined biological-function domain, to have a biological-function domain which is co-extensive with at least a portion of a metal ion-binding domain, and to be substantially more specific for one or more melanocortin receptors when in the complexed state in comparison to the uncomplexed state, to the same extent claimed by Applicants. In view of the similarity in structure between the peptides of Keri et al and Applicants' claimed peptides, the Lys residue and the D-Trp residue of the peptides of Keri et al are deemed inherently to provide an N for metal ion complexation to the same extent claimed by Applicants. Note that although the Lys and D-2-methyl-Trp residues do not provide an N for metal ion complexation in any of the examples of Keri et al, this does not mean that there are no metals or conditions under which the Lys and/or D-2-methyl-Trp residues in the peptides of Keri et al will not provide an N for metal ion complexation. Note that Applicants' claims 29 and 32 do not specify any particular metals or conditions under which metal ion complexation must occur. Sufficient evidence of similarity is deemed to be present between the peptides of Keri et al and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than the peptides of Keri et al.

18. The elected species, with the side chain limitation of instant claim 31 or the R_2 limitation of instant claims 39 and 40, is novel and unobvious over the prior art of record or any

combination thereof. Compounds having such structures are not taught or suggested in the prior art of record.

Sharma et al (U.S. Patent Application Publication 2002/0012948) is cited as art of interest, teaching peptides which anticipate the instant claims. See, e.g., Example 5. However, Sharma et al is not prior art against the instant application. Note that there is no copendency between Sharma et al and its cited provisional application, 60/112,235. Office records confirm that application 09/883,069 was not filed under 35 U.S.C. 371. It is probable that Sharma et al was intended to be a continuation or continuation-in-part of PCT/US99/29743, which itself claims priority based upon provisional application 60/112,235, even though the PCT application is not mentioned in Sharma et al's claim for priority. However, regardless of the relationship between Sharma et al and PCT/US99/29743, Sharma et al is not prior art under 35 U.S.C. 102(e) as of the filing date of the PCT application because the PCT application was filed prior to November 29, 2000. The current claims of 09/883,069 do not raise any provisional issues of obviousness-type double patenting with the instant claims.

Itaya et al (U.S. Patent No. 5,770,178) is cited as art of interest. See especially the peptide at column 11, lines 48-50. However, this peptide does not comprise a group corresponding to Applicants' R_1 group, and Itaya et al teach away from derivatizing the N-terminus of their peptides (see, e.g., column 6, lines 15-26, and Example 3).

Deghenghi is not applied against instant claim 31 because in the D-2-methyl-Trp residue, it is the non-aromatic 5-membered ring rather than the aromatic phenyl ring which is substituted by the methyl group.

Granoff et al (U.S. Patent No. 6,048,527) is cited as art of interest. See especially the peptide at column 4, lines 62-63. In this peptide, a C-terminal amide group is present at a position corresponding to Applicants' R_2 group but no amino acid with an aromatic side chain is present, and therefore the definition of R_2 as set forth in Applicants' claim 18.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

June 22, 2004